

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

DAVID BARBERIE and JANE BARBERIE,
Plaintiffs,
v.
MERCK & CO., INC., et al.
Defendants.

CIVIL ACTION No. 05-11311-REK

ANSWER TO COMPLAINT AND JURY CLAIM

Defendant Merck & Co., Inc. ("Merck") states the following, in answer to the numbered allegations set forth in the Complaint of David Barberie and Jane Barberie:

1. Defendant Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in Paragraph 1 of the Complaint.
2. Defendant Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in Paragraph 2 of the Complaint.
3. Defendant Merck denies every allegation in Paragraph 3 of the Complaint except admits that, until the voluntary withdrawal of VIOXX® on September 30, 2004, Merck did market, manufacture and distribute the prescription medicine VIOXX® for the indicated uses set out in the relevant FDA approved prescribing information. Merck further admits that Merck is a New Jersey corporation with its principal place of business at One Merck Drive, Whitehouse Station, New Jersey.
4. The allegations contained in paragraph 4 of the Complaint are legal conclusions as to which no responsive pleading is required. Should a response be deemed required, Merck denies each and every allegation contained in said paragraph except admits that Plaintiffs purport

to put more than \$75,000 in controversy but denies that there is any legal or factual basis for relief and admits that there is diversity between the parties.

FACTUAL ALLEGATIONS

5. Defendant Merck denies every allegation in Paragraph 5 of the Complaint except admits that the Plaintiff purports to bring an action arising from the sales and efficacy of VIOXX®, that VIOXX® is a selective COX-2 inhibitor, and that and, until the voluntary withdrawal of VIOXX® on September 30, 2004, Merck did market VIOXX® for the indicated uses set out in the relevant FDA approved prescribing information. Merck respectfully refers the Court to the FDA prescribing information for VIOXX®'s indicated uses.

6. Defendant Merck denies every allegation in Paragraph 6 of the Complaint except admits that Merck sought and, in 1999, received FDA approval to manufacture and market the prescription medicine VIOXX®. Merck further admits that VIOXX® is the brand name for rofecoxib.

7. Defendant Merck denies every allegation in Paragraph 7 of the Complaint except admits that Merck sought and, in 1999, received the approval of the United States Food and Drug Administration ("FDA") to manufacture and market the prescription medicine VIOXX®.

8. Defendant Merck denies every allegation in Paragraph 8 of the Complain.

9. Defendant Merck denies every allegation in Paragraph 9 of the Complaint.

10. Defendant Merck denies every allegation in Paragraph 10 of the Complaint.

11. Defendant Merck denies every allegation in Paragraph 11 of the Complaint except admits that the studies referenced in the first sentence of Paragraph 11 and the article referenced in the second sentence of Paragraph 11 exist, and Merck respectfully refers the Court to said publications for their actual language and full text.

12. Defendant Merck denies every allegation in Paragraph 12 of the Complaint.

13. Defendant Merck denies every allegation in Paragraph 13 of the Complaint except admits that the referenced publication exists, and Merck respectfully refers the Court to said publication for its actual language and full text.

14. Defendant Merck denies every allegation in Paragraph 14 of the Complaint except admits that the referenced study exists, and Merck respectfully refers the Court to said study for its actual language and full text.

15. Defendant Merck denies every allegation in Paragraph 15 of the Complaint except admits that the referenced studies exist, and Merck respectfully refers the Court to said studies for their actual language and full text.

16. Defendant Merck denies every allegation in Paragraph 16 of the Complaint except admits that the referenced study exists, and Merck respectfully refers the Court to said study for its actual language and full text.

17. Defendant Merck denies every allegation in Paragraph 17 of the Complaint except admits that Merck received a letter from a regulatory review officer in September 2001, and Merck respectfully refers the Court to that letter for its actual language and full text.

18. Defendant Merck denies every allegation in Paragraph 18 of the Complaint except admits that in April 2002 the FDA approved certain changes to the VIOXX® prescribing information, and Merck respectfully refers the Court to the prescribing information for VIOXX® for its actual language and full text.

19. Defendant Merck denies every allegation in Paragraph 19 of the Complaint except admits that on September 30, 2004 Merck announced the voluntary worldwide withdrawal of VIOXX®, and Merck respectfully refers the Court to the referenced announcement for its actual

language and full text. Merck further avers that it announced on September 30, 2004 that in a prospective, randomized, placebo-controlled clinical trial there was an increased relative risk for confirmed cardiovascular events beginning after 18 months of treatment in the patients taking VIOXX®, compared with those taking placebo, and that Merck concluded that given the availability of alternative therapies and questions raised by the data from that trial, a voluntary withdrawal of VIOXX® best served the interests of patients.

20. Defendant Merck denies every allegation in Paragraph 20 of the Complaint.
21. Defendant Merck denies every allegation in Paragraph 21 of the Complaint.
22. Defendant Merck denies every allegation in Paragraph 22 of the Complaint.
23. Defendant Merck denies every allegation in Paragraph 23 of the Complaint.
24. Defendant Merck denies every allegation in Paragraph 24 of the Complaint.
25. Defendant Merck denies every allegation in Paragraph 25 of the Complaint.
26. Defendant Merck denies every allegation in Paragraph 26 of the Complaint.

COUNT I: NEGLIGENCE

27. Defendant Merck hereby incorporates by reference the preceding specific responses to the allegations in Paragraphs 1 through 26 of the Complaint.
28. Defendant Merck denies every allegation in Paragraph 28 of the Complaint.
29. The allegations in Paragraph 29 are legal conclusions as to which no responsive pleading is required. Should a response be deemed required, Defendant Merck denies every allegation in Paragraph 29 of the Complaint.
30. Defendant Merck denies every allegation in Paragraph 30 of the Complaint, including subparts a-i.
31. Defendant Merck denies every allegation in Paragraph 31 of the Complaint.

32. Defendant Merck denies every allegation in Paragraph 32 of the Complaint.

COUNT II: BREACH OF WARRANTY

33. Defendant Merck hereby incorporates by reference the preceding specific responses to the allegations in Paragraphs 1 through 32 of the Complaint.

34. The allegations in Paragraph 34 are legal conclusions as to which no responsive pleading is required. Should a response be deemed required, Defendant Merck denies every allegation in Paragraph 34 of the Complaint.

35. Defendant Merck denies every allegation in Paragraph 35 of the Complaint.

36. Defendant Merck denies every allegation in Paragraph 36 of the Complaint.

37. Defendant Merck denies every allegation in Paragraph 37 of the Complaint.

38. Defendant Merck denies every allegation in Paragraph 38 of the Complaint.

39. Defendant Merck denies every allegation in Paragraph 39 of the Complaint.

40. Defendant Merck denies every allegation in Paragraph 40 of the Complaint.

COUNT III: CONSORTIUM

41. Defendant Merck hereby incorporates by reference the preceding specific responses to the allegations in Paragraphs 1 through 40 of the Complaint. Defendant Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in the second sentence of Paragraph 41 of the Complaint.

42. Defendant Merck denies every allegation in Paragraph 42 of the Complaint.

RESPONSE TO "JURY DEMAND"

Merck admits that the Plaintiff demands a trial by jury.

JURY DEMAND

Merck hereby requests a trial by jury.

DEFENSES

FIRST DEFENSE

The Complaint fails to set forth a cause of action upon which relief can be granted.

SECOND DEFENSE

Any product for which Defendant Merck was responsible at the time of the occurrence or injuries alleged by the Plaintiff was not defective and unreasonably dangerous in its design, manufacture, or marketing, and was at all times reasonably safe and reasonably fit for its intended use. The warnings and instructions accompanying the product or products at issue at the time of the occurrence or injuries alleged by the Plaintiff were legally adequate warnings and instructions.

THIRD DEFENSE

The occurrence and injuries alleged by the Plaintiff were caused or contributed to by the negligence, breaches of warranty, or defective products of the Plaintiff and/or third parties over whom Merck had no control and for whom Merck is not responsible.

FOURTH DEFENSE

If the Plaintiff has sustained injuries or losses as alleged in the Complaint, upon information and belief, such injuries and losses were caused by the actions of persons having no real or apparent authority to take said actions on behalf of Merck and over whom Merck had no control and for whom Merck may not be held accountable.

FIFTH DEFENSE

The occurrence and injuries alleged by the Plaintiff resulted from an intervening cause or a new and independent cause which was the proximate and/or producing cause and/or the sole proximate and/or sole cause of the occurrence and injuries alleged by the Plaintiff. Moreover,

the occurrence and injuries were caused by separate and independent events or agencies not reasonably foreseeable. Such separate and independent events or agencies destroy the causal connection, if any, between any breach of legal duty on the part of Merck and the occurrence and injuries alleged by the Plaintiff, and thereby become the immediate and/or sole cause, and/or sole proximate and/or sole producing cause of such occurrence and injuries, relieving Merck of liability to the Plaintiff or any other parties.

SIXTH DEFENSE

If the Plaintiff sustained the injuries or incurred the expenses alleged, the same were caused, in whole or in part, by operation of nature or an act of God.

SEVENTH DEFENSE

If the Plaintiff sustained the injuries or incurred the expenses alleged, the same were caused by an idiosyncratic reaction, without any negligence, defect, or failure on the part of Merck.

EIGHTH DEFENSE

The injuries and damages alleged in the Plaintiff's Complaint were the result of unavoidable circumstances that could not have been prevented by anyone, including Merck.

NINTH DEFENSE

Any and all damages alleged by the Plaintiff were caused by misuse of the product or products at issue in this case, failure to use the product or products properly, and/or alteration or negligent use of the product or products.

TENTH DEFENSE

The Plaintiff cannot recover under the Complaint because the product at issue was made in accordance with the state of the art at the time it was manufactured.

ELEVENTH DEFENSE

The Plaintiff's claims are barred by the Plaintiff's contributory negligence and the contributory negligence of others.

TWELFTH DEFENSE

The Plaintiff's claims are barred by the Plaintiff's express and/or implied assumption of the risks, if any, inherent in the alleged use of the product or products at issue.

THIRTEENTH DEFENSE

Each and every claim asserted or raised in the Complaint is barred by the doctrine of laches.

FOURTEENTH DEFENSE

The benefits of the product or products at issue outweigh the risks, if any, that may be attendant to their use.

FIFTEENTH DEFENSE

The damages and injuries alleged, if any, were caused or enhanced by a preexisting medical condition of the Plaintiff that was not related to any product manufactured by Merck.

SIXTEENTH DEFENSE

Each and every claim asserted or raised in the Complaint is barred by the doctrine set forth in Comment k of the Restatement (Second) of Torts § 402A as to the product or products at issue.

SEVENTEENTH DEFENSE

The Plaintiff's claims are barred in whole or in part pursuant to comment f to Section 6 of the Restatement (Third) of Torts: Product Liability.

EIGHTEENTH DEFENSE

The Plaintiff's claims are barred in whole or in part pursuant to comment j to Section 402A of the Restatement (Second) of Torts.

NINETEENTH DEFENSE

The Plaintiff's claims are barred under Section 4 et seq. of the Restatement (Third), of Torts: Product Liability.

TWENTIETH DEFENSE

Any warnings that Merck gave were transmitted to the prescribing physicians and/or health care providers, and under Massachusetts law Merck's obligation is to warn only the prescribing physician and/or health care providers and said obligation was fulfilled.

TWENTY-FIRST DEFENSE

Merck has complied with all requirements of the Food and Drug Administration of the United States Department of Health and Human Services, and the product or products at issue were approved pursuant to the applicable statutes and regulations. Pursuant to such, the product or products at issue could only be used pursuant to the prescription of a licensed prescriber. The package insert for the product or products at issue was also approved by the Food and Drug Administration, and the marketing was conducted in conformity with the regulations of the Food and Drug Administration. Therefore, the Plaintiff's claims are preempted.

TWENTY-SECOND DEFENSE

The Plaintiff's claims are barred by the applicable statute(s) of limitations.

TWENTY-THIRD DEFENSE

If the Plaintiff sustained the injuries and damages alleged in the Complaint, such injuries resulted, in whole or in part, from the negligence or fault of the Plaintiff and/or third parties, not

from any negligence or breach of duty by Merck. Judgment may not enter for the Plaintiff if it is found that the Plaintiff was more negligent than Merck. If judgment is rendered in the Plaintiff's favor, the amount of such judgment must be reduced under the doctrine of comparative negligence.

TWENTY-FOURTH DEFENSE

Merck is unaware at this time of any settlement by any alleged joint tortfeasor. However, in the event any settlement is or has been made by any alleged joint tortfeasor, Merck is entitled to a credit/offset for such settlement.

TWENTY-FIFTH DEFENSE

The extent of any risk associated with the use of Merck's product, the existence of which is not admitted, was, at the time of the distribution of the product by Merck, unknown and could not have been known by the use of ordinary care by Merck.

TWENTY-SIXTH DEFENSE

At the time the product at issue was manufactured, there was no practical and technically feasible alternative design or formulation that would have prevented the alleged harm without substantially impairing the usefulness of the product.

TWENTY-SEVENTH DEFENSE

Merck made no express or implied representations or warranties of any kind to the Plaintiff, nor did the Plaintiff rely on any representations or warranties made by Merck. To the extent the Plaintiff relied on any representations or warranties, such reliance was unjustified.

TWENTY-EIGHTH DEFENSE

Merck did not breach any duty of care to the Plaintiff.

TWENTY-NINTH DEFENSE

The Plaintiff's claims are barred by the doctrine of estoppel.

THIRTIETH DEFENSE

The Plaintiff's claims are barred by the doctrine of waiver.

THIRTY-FIRST DEFENSE

The Plaintiff has failed to join all necessary and indispensable parties.

THIRTY-SECOND DEFENSE

The Plaintiff's claims are barred because the Plaintiff has failed and refused to mitigate her alleged damages.

THIRTY-THIRD DEFENSE

Merck did not violate any state or federal statute, regulation or ordinance to cause the Plaintiff's alleged injuries.

THIRTY-FOURTH DEFENSE

The Plaintiff's claims are barred in whole or in part due to a lack of notice.

THIRTY-FIFTH DEFENSE

To the extent that the Plaintiff asserts claims based on Merck's adherence to and compliance with applicable state laws, regulations, and rules, such claims are preempted by federal law under the Supremacy Clause of the United States Constitution.

THIRTY-SIXTH DEFENSE

The Plaintiff's claims are barred, in whole or in part, because the Plaintiff lacks capacity and/or standing to bring such claims.

THIRTY-SEVENTH DEFENSE

To the extent the Plaintiff is seeking recovery for benefits entitled to be received or actually received from any other source for injuries alleged in the Complaint, such benefits are

not recoverable in this action.

THIRTY-EIGHTH DEFENSE

The Plaintiff's state-law claims are barred, in whole or in part, because VIOXX® was subject to and received pre-market approval by the FDA under 52 Stat. 1040, 21 U.S.C. § 301.

THIRTY-NINTH DEFENSE

The Complaint and the causes of action contained therein are barred in whole or in part by the United States and Massachusetts Constitutions, which prohibit the extraterritorial application of Massachusetts law.

FORTIETH DEFENSE

The Complaint and the causes of action contained therein are barred in whole or in part by the U.S. Constitution, article I, section VIII, clause 3 to the extent they seek to regulate Merck's practices outside of Massachusetts. That constitutional provision prohibits a State from regulating conduct that occurs wholly outside of its borders.

FORTY-FIRST DEFENSE

Merck hereby gives notice that it intends to rely upon such other defenses as may become available or appear during discovery proceeding in this case or that are included in the master answer to be filed in the Multidistrict Litigation proceeding before Judge Fallon of the Eastern District of Louisiana. Merck hereby reserves the right to amend its answer to assert any such defense.

WHEREFORE, Defendant Merck & Co. respectfully requests that the Plaintiff take nothing in this suit, that it recover its costs of court and expenses and such other relief to which it may show itself justly entitled.

Respectfully submitted,

/s/ Lucy Fowler

James J. Dillon (BBO# 124660)
Lucy Fowler (BBO# 647929)
Kalun Lee (BBO# 657489)
FOLEY HOAG LLP
155 Seaport Boulevard
Boston, MA 02110-2600
(617) 832-1000

Counsel for Merck & Co., Inc.

Dated: September 6, 2005

CERTIFICATE OF SERVICE

I certify that a true copy of the foregoing document was served on September 6, 2005 electronically upon:

Alan L. Cantor, Esq.
Swartz & Swartz
Ten Marshall Street
Boston, MA 02108

/s/ Lucy Fowler